

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

PAMELA BUTLER, et al.,

Plaintiffs,

v.

MALLINCKRODT LLC, et al.

Defendants.

)

)

) Case No. 4:18-cv-01701-AGF

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) Lead Case

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ORAL ARGUMENT REQUESTED

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**DEFENDANTS' JOINT MEMORANDUM IN
SUPPORT OF THEIR MOTION TO EXCLUDE THE
TESTIMONY OF PLAINTIFFS' EXPERT HOWARD HU, M.D.**

Defendants Mallinckrodt LLC (“Mallinckrodt”) and Cotter Corporation (N.S.L.) (“Cotter”) jointly move the Court for an Order excluding the testimony of Plaintiffs’ causation expert, Howard Hu, M.D., because he is not qualified to opine on causation and his opinions and bases do not satisfy the requirements of Federal Rule of Evidence 702 or *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

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I. INTRODUCTION

This is a consolidated toxic tort case brought by four plaintiffs seeking damages from exposure to radiation under the Price-Anderson Act, 42 U.S.C. § 2011, *et seq.* The four Plaintiffs allege radiation exposure caused their respective breast, brain, and lymphoma cancers and an unspecified brain tumor. Plaintiffs designated Howard Hu, M.D.—a medical doctor with no specialized training in health physics, radiation sources, modeling, or oncology—to opine on causation, and Dr. Hu seeks to offer his “best guess” that radiation caused the three cancers and tumor. Dr. Hu’s opinions are contained in four reports, one for each Plaintiff, and four addenda to those reports. While Dr. Hu’s reports were timely produced on April 1, 2019, his untimely addenda were produced six months later on September 30, 2019.

This Court should strike Dr. Hu’s speculative and baseless specific causation opinions for these four Plaintiffs because he is not qualified to offer them and they are not reliable or relevant for the following reasons:

- Dr. Hu’s specific-causation methodology is unreliable because no epidemiology supports his opinion, he admitted the “natural background” level of radiation he uses is contradicted by every authoritative source, the assumptions on which his opinion is based are completely unsupported and he ignored, without explanation, contradictory opinions in the sources he cited.
- Dr. Hu did not rule out alternative causes.
- Dr. Hu’s opinions that the Plaintiffs were exposed to radiation in amounts less than natural background are not relevant under the Price-Anderson Act.
- Dr. Hu’s untimely Addendum opinions are also unreliable and the Court should exclude them.
- Dr. Hu is ultimately not qualified to opine on specific causation.

II. BACKGROUND

Plaintiffs are four individuals alleging that exposure to Coldwater Creek radiation caused their four distinct illnesses. (Doc. #1, ¶ 24.) As the expert charged with analyzing general and

specific causation, Dr. Hu was responsible for determining whether ionizing radiation can even cause breast cancer, brain cancer, Mantle Cell Lymphoma (“MCL cancer”), or the unidentified tumor (general causation). If Dr. Hu determined ionizing radiation can cause those three cancers (he does), then for specific causation he was to analyze whether the ionizing radiation the Plaintiffs were allegedly exposed to from Coldwater Creek actually did cause their respective cancer (specific causation). Dr. Hu ultimately opined that Plaintiffs’ exposure to Thorium-230, Radium-226, and Uranium-238 from Coldwater Creek did in fact cause their illnesses.

Dr. Hu professed to reach this conclusion by accepting as true the doses based on a Reasonable Maximum Exposure (“RME”) calculated by Plaintiff’s expert James Clark, Ph.D.,¹ comparing Dr. Clark’s doses to Dr. Clark’s fabricated natural background, reviewing relevant epidemiology, and then finally considering other factors that could have caused these cancers.² The facts show otherwise. What Dr. Hu actually did was: (1) reviewed Dr. Clark’s doses and discovered “obvious errors” in them; (2) compared Dr. Clark’s erroneous doses to Dr. Clark’s background level (even though he understood that Dr. Clark’s fabricated “background” was contradicted by every authoritative radiation source); (3) reviewed relevant epidemiology and discovered that there is not a single epidemiological study that identifies a causative relationship between Dr. Clark’s doses and any cancer; and (4) then failed to actually consider or address any of the other possible factors that could have caused these cancers.

Dr. Hu should be excluded for his failings in each of the four preceding steps. He knew Dr. Clark’s work was riddled with errors, yet he still relied on it. He knew Dr. Clark’s “background”

¹ Defendants are concurrently filing a motion to exclude the testimony of Dr. Clark because it is also unreliable for the reasons stated in that motion.

² Hu’s April 1, 2019 Reports for each Plaintiff, Section III.B, attached as **Exhibits A-1, A-2, A-3, A-4**, respectively.

radiation value was wrong, yet he relied on it for his risk assessment. (Hu *Butler* 95:25—96:13, attached as **Exhibit B**.) He knew there was no epidemiology to support his causation opinion before he issued his reports. He never considered other possible causal factors because he never looked for any. In short, Dr. Hu started with the assumption that the radiation exposures alleged in this case caused Plaintiffs’ cancers, and he ignored everything that demonstrated the assumption was patently false. This approach is the antithesis of science.

Six months after issuing his original reports, Dr. Hu issued an addendum to each.³ Dr. Hu did so because he realized Dr. Clark’s RME-based doses (the original doses on which Dr. Hu based his opinions) were insignificant (*i.e.*, not high enough to have any remotely plausible chance of causing Plaintiffs’ cancers or tumor.) In his addenda, he ignored Dr. Clark’s opinion and independently opined that a different dose, buried in Dr. Clark’s appendices, was the proper dose to analyze causation. (Hu *Butler* 212:14—213:3.) These were Dr. Clark’s “maximum” doses, which are orders of magnitude higher than Dr. Clark’s RME-based doses (which, again, stands for Reasonable **Maximum** Exposure). (See Hu *Czapla* 8/31/20, 47:6–25, attached as **Exhibit C**.) However, Dr. Hu did not investigate the assumptions underlying these maximum doses and did not even realize at the time he issued his addenda that these maximum doses are based on a scenario that requires each Plaintiff to be in three different places at the same time for their entire exposure—a scenario Dr. Hu eventually admitted was impossible.

Each of Dr. Hu’s erroneous assumptions, mistakes, and methodological errors discussed below ultimately show, in addition to his lack of training and experience, that Dr. Hu is simply not qualified to opine on specific causation in this case.

³ See Hu’s September 30, 2019 addendum for each Plaintiff.

III. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Under Rule 702, a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based upon sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 imposes a “gate-keeping function” on district courts to ensure that “any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert*, 509 U.S. at 589. “The objective of the *Daubert* inquiry ‘is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 722 (8th Cir. 2015) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Moreover, the party offering the expert testimony bears the burden of establishing its admissibility. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 589–90).

Daubert enumerates several non-exclusive factors to guide this Court’s reliability analysis:

- whether the expert’s technique or theory can be or has been tested—that is, whether the expert’s theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability,
- whether the technique or theory has been subjected to peer review or publication,
- the known or potential rate of error of the technique or theory when applied,
- the existence and maintenance of standards and controls, and

- whether the technique or theory has been generally accepted in the scientific community.

Daubert, 509 U.S. at 593–94; Fed. R. Evid. 702, advisory committee’s notes. “*Daubert’s* progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Lauzon v. Senco Prods, Inc.*, 270 F.3d 681, 687 (8th Cir. 2001).

Further, “[w]hen the analytical gap between the data and proffered opinion is too great, the opinion must be excluded.” *Marmo*, 457 F.3d at 758. And when an opinion rests on faulty or insufficient data, or otherwise ignores relevant data, the district court should exclude the testimony. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000).

IV. ARGUMENTS & AUTHORITIES

A. Dr. Hu’s Specific Causation Methodology Is Unreliable Because It Relies on Dr. Clark’s Unreliable Doses, Is Unsupported by Epidemiology, Adopts Dr. Clark’s Flawed Work Without Validation, and Contradicts the Sources on Which it Rests.

In each of his four reports, Dr. Hu opined that: (1) the Plaintiff had significant exposure to radiation as calculated by Dr. Clark; (2) the “high exposure” specifically included an exposure to each Plaintiff’s cancerous organ multiple times above background levels of radiation; (3) the exposure occurred during childhood, where applicable, and (4) there were no other risk factors to explain how the Plaintiff’s cancer was caused. (Hu, April 1, 2019 Reports, Section III.B). His opinions necessarily rely on Dr. Clark’s doses.⁴ Because those doses are unreliable for the reasons

⁴ See, e.g., Hu *Butler* 257:25 (“A. I’m not the exposure assessor”); *id.* 119:6–9 (“Q. . . . you’re relying on Dr. Clark for exposure numbers; right? A. Yes.”); *id.* 248:6–11 (“Q. Now, you said you relied on Dr. Clark’s reports for your analysis; correct? A. Yes. Q. And if there were errors

discussed in the Clark *Daubert* motion, Dr. Hu's derivative opinions are completely unsupported and fail. However, Dr. Hu's opinions independently suffer from additional distinct failures that make them inadmissible under Rule 702.

1. Dr. Hu Admitted There Are Errors in Dr. Clark's Assumptions, Relied on Them Anyway, and Conducted No Validation Assessment.

Experts who rest their opinions on the work of other experts without validating the underlying assumptions of their opinions are subject to exclusion. *In re TMI Litig.*, 193 F.3d 613, 715 (3d Cir. 1999), *amend.* 199 F.3d 158 (3d Cir. 2000) (excluding experts in Price-Anderson case for, among other reasons, blindly relying on the work of other experts in the case). In *TMI*, the court determined that an expert was unreliable because "his failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinion, demonstrates that the methodology he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results." *Id.*

So too here. Dr. Hu admits that there were "obvious errors" in Dr. Clark's work, which he relied upon regardless. (Hu *Butler* 119:20–120:9; 124:12–17.) For example, Dr. Hu knowingly relied on the "committed doses" based on the Reasonable Maximum Exposure⁵ ("RME") Dr. Clark developed. (Hu *Butler* 141:8—142:10). Committed doses by definition include a 70-year exposure period.⁶ However, all of the Plaintiffs developed cancer before they were 70, meaning the doses

in his report, that would affect your analysis; correct? A. They may."); *id.* 119:10–12 ("Q. You understand your opinions are only as good as [Dr. Clark's] numbers? A. Yes.").

⁵ RME doses are problematic in and of themselves because, as discussed in the Motion to Exclude Dr. Clark, they calculate the highest exposure that is reasonably expected to occur at a site, using the upper confidence limit of the average, which is well above the average. (Clark *Butler* 82:1 – 84:3, attached as **Exhibit D**.)

⁶ The committed effective dose from intakes of radionuclides is also used in prospective dose estimates for members of the public. In these cases, a commitment period of 50 years is recommended for adults. For infants and children, the dose is evaluated to the age of 70 years.

Dr. Hu relies on for his specific causation period include exposures that would have occurred post-diagnosis—*i.e.*, that could not have caused or contributed to their illness under any circumstances. Further, none of the Plaintiffs were older than 70 when they were diagnosed, nor did any of them live in the exposure area for 70 years, meaning the exposure Dr. Hu relied on does not match their testimony or the facts. (Hu *Butler* 142:4–10.) In reality, their exposure periods, even as alleged, were much lower—Plaintiff Walick’s, for example, was 9 years.⁷ (Hu *Butler* 141:8–142:7.) Dr. Hu admits that there is no literature to support the use of a 70-year dose to determine causation for shorter exposure periods. (Hu *Butler* 143:3–22.) He also acknowledges that it is “perhaps not” appropriate to use a 70-year dose for exposure periods that are 1–6 *decades* shorter, like those for these Plaintiffs. (Hu *Butler* 142:11–143:22.) Despite these admissions, Dr. Hu relied on Dr. Clark’s 70-year doses anyway. (Hu *Butler* 119:16–25.)

Dr. Hu also recognized but did not correct Dr. Clark’s failure to incorporate a standard “latent period.” As Dr. Hu testified, both here and in *Strong*,⁸ there is generally a ten-year latent period between exposure to and clinical diagnosis of a radiation-induced cancer. (Hu *Butler* 140:15–141:7; Hu *Strong* 78:12–19, attached as **Exhibit E**.) The exposure period must therefore end ten years before diagnosis. (Mettler-Royal March 17, 2020 Report, p. 11, attached as **Exhibit**

ICRP, 2015. Occupational Intakes of Radionuclides: Part 1. ICRP Publication 130. Ann. ICRP 44(2).

⁷ The factual exposure periods for the three other plaintiffs, properly accounting for the 10-year latent period, are: Hines—25 years; Koterba—57 years; and Butler—10 years. (RAC’s March 17, 2020 Report, Table 12-1.)

⁸ “*Strong*” refers to the case *Don Strong, et al. v. Republic Services, Inc. et al.* in the Circuit Court of St. Louis County, Missouri. *Strong* involved similar allegations of radiation exposure but the origin was West Lake Landfill, not Coldwater Creek. As here, Plaintiffs in *Strong* designated Dr. Hu as a general and specific causation expert. Mallinckrodt was not involved in the *Strong* case and did not attend Dr. Hu’s deposition in that case, which was held on September 16 and 17, 2019. Both Mallinckrodt and Cotter were present at Dr. Hu’s October 9, 2019 deposition in this case.

F.) Dr. Hu did not account for a latent period because he relied exclusively on Dr. Clark's doses, which did not factor in any latency period. (Hu *Butler* 144:2–5.)

Dr. Hu further admitted that he did not validate Dr. Clark's assumptions or methodology in any way:

Q. Did you do anything to validate Dr. Clark's work?

A. I just read his report to see whether the overall methodology was – comports with what I understand an exposure assessment report should look like. That's all.

Q. Okay. Did you do anything to validate his numbers?

A. No.

Q. All right. And you took his numbers for what they are?

A. Yes.

(*Id.* 119:13–25.) At bottom, Dr. Hu tried to shirk all responsibility for Dr. Clark's errors by saying the exposure assessment was not his “area.” (Hu *Butler* 119:20–120:9; 124:12–17.) But Dr. Hu's “unblinking reliance,” *In re TMI Litig.*, 193 F.3d at 715, on Dr. Clark's opinions despite acknowledging “obvious errors” in his work (Hu *Butler* 120:1–3) warrants exclusion. Just like the excluded expert in *TMI*, Dr. Hu failed to properly validate the methodology underlying the doses on which his opinions rest.

2. Dr. Hu Admits No Epidemiological Studies Support His Specific Causation Opinion in this Case.

Dr. Hu's opinion should also be excluded because he has not shown the error-ridden doses he is relying on are capable of causing these cancers. “The primary basis to link specific cancers with radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation.” *In re TMI Litig.*, 193 F.3d at 643. “In other

words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation.” *Id.*

Dr. Hu opined that the following doses caused or contributed to Plaintiffs’ cancers: 2.4 millirem to the brain, 16.3 millirem to the brain, 6.8 millirem to the breast, and 131 millirem to the lymph nodes. (Hu April 1, 2019 Reports, Section II.B.) But Dr. Hu admitted that these opinions are not supported by *any* data in the relevant epidemiological literature:

Q. Can you cite to any study that states a committed dose of 2.4 millirem to the brain can cause brain cancer?

A. Of course not. That’s a low dose, and an epidemiologic study would simply not have the power to detect that.

Q. The same for 16.3 millirem to the brain?

A. Correct.

Q. The same with 6.8 to the breast?

A. It’s probably true.

Q. Can you cite to any study that states a committed dose of 131 millirem to the lymph nodes can cause MCL?

A. Same issue.

(Hu *Butler* 110:18–111:6.)

And even using Dr. Clark’s admittedly impossible “maximum” dose figures (21–71 millirem to the brain, 45.2–272 millirem to the brain, 197 to 1,290 millirem to the breast, and 19,300 to 43,900 millirem to the lymph nodes), Dr. Hu could not cite any data or studies supporting a conclusion that those doses caused Plaintiffs’ cancers:

Q. Can you cite to any study that states an annual whole-body dose of 18.7 millirem for lifetime can cause any type of cancer or tumor?

A. Not as I sit here today.

Q. 180?

A. I'd have to look at the literature again.

Q. 2,000?

A. Counselor, that's not something that I've reviewed lately, so I can't give an opinion on that.

Q. 20,000?

A. I'm not prepared to give you an opinion on that.

(Hu *Butler* 113:11–17; *see also id.* 224:16–25.)

This testimony is fatal to Dr. Hu's opinion. He has no authority to connect the extremely low exposures in this case to any of Plaintiffs' cancers, nor does he even know what dose could cause any type of cancer up through even 20,000 millirem. Without any epidemiology to support his specific causation opinion that these doses caused the Plaintiffs' cancers, Dr. Hu's opinion is nothing more than speculation and should be excluded. *See In re TMI Litig.*, 193 F.3d at 643; *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 898 (8th Cir. 2008) (opinions excluded because "the gap between the data identified and [the expert's] opinion was simply too great an analytical gap . . . to support admissibility" (internal quotations omitted)).

3. Dr. Hu's Causation Analysis Is Unreliable Because It Relies on a Fictitious "Natural Background" Level of Radiation.

Dr. Hu's reliance on Dr. Clark's fictitious background levels of radiation—despite admitting that it was not supported in scientific literature—is fatal to his specific causation opinion for at least two reasons. First, there is no scientific authority to support the fictitious background levels, and in fact all governing scientific authority contradicts Dr. Hu and Dr. Clark. Second, Dr. Hu intentionally incorporated Dr. Clark's fictitious background radiation levels to generate litigation-inspired risk levels significantly higher than that universally accepted in the scientific community.

One element of Plaintiffs' burden of proof in this case is an obligation to show they were exposed to radiation in an amount above natural background radiation. *In re TMI Litig.*, 193 F.3d at 659. As Dr. Hu admits (Hu *Butler* 97:12–19; 95:25–97:19), “natural background” is a defined term in radiation science which, according to the Environmental Protection Agency (“EPA”), the Agency for Toxic Substances and Disease Registry (“ATSDR”), and many other authoritative legal and scientific sources, means an effective dose of approximately 360 millirem per year.⁹ (*See also* Hu *Czapla* 9/1/20, 133:2–15, attached as **Exhibit G** (acknowledging it is “generally known” that background levels of radiation are roughly 300 millirem).) Both *TMI* and *McMunn* adopted this number during their Price-Anderson Act litigation. *See In re TMI Litig.*, 193 F.3d at 659 (the total average annual dose, from both natural radiation and man-made radiation, is 360 millirem); *McMunn v. Babcock & Wilcox Power Generation Group, Inc.*, 131 F. Supp. 3d 352, 396 (W.D. Penn. 2015) (same). Yet Dr. Hu and Dr. Clark reject this number.

Dr. Hu formed his causation opinions by comparing each Plaintiffs' RME, and later an impossible “maximum” exposure dose value, to Dr. Clark's “natural background” exposure levels. (Hu *Butler* 95:13–20.) But Dr. Hu failed to use the scientifically accepted level of 360 millirem for natural background. Instead, he knowingly relied on a method invented by Dr. Clark for this litigation. To calculate “natural background” for these cases, Dr. Clark created new numbers by looking only at select radionuclides, which generated a range between 0.9 and 55 millirem for

⁹ Natural background varies by geographic location. For example, citizens of Denver, Colorado, receive approximately 618 millirem per year of natural background compared to 403 millirem in St. Louis. Clark *Butler* Dep. 161:13-162:1 (Sept. 18, 2019). The accepted background amount has increased in recent years to 620 millirem to account for the everyday exposure to manmade radiation sources, most of which is due to medical radiation. The U.S. Nuclear Regulatory Commission, the Environmental Protection Agency, Department of Energy, the Occupational Safety and Health Administration, and many others now report 620 millirem as the annual average exposure most people receive from ionizing radiation.

Plaintiffs’ *entire* exposure period. (Hu *Butler* 97:16–19; Hu April 1, 2019 Reports, Section II.B.) To put Dr. Clark’s “natural background” in context, where the entire scientific and radiological community would calculate each plaintiff’s natural background by multiplying every exposure year by 360 millirem (e.g., a 10-year exposure equals 3,600 millirem of background radiation),¹⁰ Dr. Clark’s approach to “natural background” reduced this total number to *at most* 55 millirem.

Dr. Hu admitted he has never seen anyone use natural background as Dr. Clark did, nor does he know how Clark calculated his version of it. (Hu *Butler* 97:12–19; 108:19–109:10; 110:1–16.) Yet despite these red flags of unreliability, Dr. Hu adopted Dr. Clark’s “natural background” levels without question to support his causation opinion that Plaintiffs’ exposure doses are “high” compared to the fictitious, made-for-litigation background levels, rather than those reported in reliable legal and scientific sources. (Hu *Butler* 95:9–20.)

The significance of Dr. Clark’s fictional natural background values and Dr. Hu’s willingness to use them—despite his own admission that doing so is inconsistent with all accepted scientific authorities—cannot be overstated. These fabricated numbers drive Dr. Hu’s causation opinion—and they defeat its reliability. In short, the “natural background” levels Dr. Hu relied on (1) have not been subjected to peer review or publication; (2) are not generally accepted (or accepted at all) in the scientific community; and (3) are exactly the type of unsupported, invented-for-litigation opinion that should be excluded under *Daubert*. *Castellow v. Chevron USA*, 97 F.

¹⁰ *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D.Tex. 2005), was a Price-Anderson Act case involving allegations of Uranium exposure in which the Court excluded the plaintiffs’ causation expert for improperly comparing the plaintiffs’ cumulative exposure to a single year of background. *Id.* at 858. The Court noted in doing so, the expert was effectively comparing “apples to oranges” and made the same analogy presented here that natural background must be calculated across the entire exposure period for a proper comparison. *Id.* In that case the Court identified background in Karnes County, Texas at 250 millirem and that over ten years it would be 2,500 millirems. *Id.*

Supp. 2d 780, 786 (S.D. Tex. 2000) (“work[ing] backward” from conclusion to find scientific support is a practice that “cannot withstand *Daubert* scrutiny and is not due any credence in a court of law”); *see also Lauzon*, 270 F.3d at 692 (“That an expert testifies based on research he has conducted independent of litigation provides important, objective proof that the research comports with the dictates of good science.”).

4. Dr. Hu’s Opinion Is Unreliable Because He Defied Contradictory Instructions in the Very Same Source He Relied on For His Opinion.

Not only is there *no* authoritative source supporting Dr. Hu’s specific causation opinion in this case, but the primary source Dr. Hu relies on for specific causation, the ATSDR’s Public Health Assessment for Coldwater Creek (“Final ATSDR Report”), admonishes against conducting the very analysis Dr. Hu performed. (Final ATSDR Report, April 2019, attached as **Exhibit H**.) The Final ATSDR Report states explicitly that its methodology does not apply to individuals. Dr. Hu acknowledged the ATSDR report states that “we recognize that this approach would not be used in a detailed dose reconstruction” and that “the estimated exposures do not apply to individuals or even an average individual.” (Hu *Butler* 130:2–131:17.) But Dr. Hu admitted that he and Dr. Clark did exactly what the ATSDR Report prohibits. *Id.*

Moreover, the Final ATSDR Report relies on an exposure level called a Minimum Risk Level (“MRL”), which defines the point at which the dose is so low that no harm could be expected to come of it. (Final ATSDR Report, April 2019, p. 29.) The MRL, which is used by the U.S. Department of Energy and the U.S. Nuclear Regulatory Commission in addition to the ATSDR, is 100 millirem per year. *Id.*; *see also* 10 C.F.R. §§ 20, 835. The MRL is a fraction of the average annual effective dose in the United States (360 millirem) from natural background. (Final ATSDR Report, April 2019, p. 29 n.5; Hu *Butler* 97:17–100:18.) The ATSDR concluded this was an

appropriate exposure to adjudge risk because “no harmful effects have been shown to be associated with this dose.” (Final ATSDR Report, April 2019, p. 29 n.5.)

And yet Dr. Hu opines that each of Plaintiffs’ exposures caused their cancers—even though their RME exposures that Dr. Clark developed allegedly using the ATSDR methodology (and on which Hu relied) are less than the universally accepted MRL of 100 millirem per year.¹¹ In short, in direct contradiction to the ATSDR Report on which his opinion relies, Dr. Hu found cancer *causation* where the ATSDR declared there could not even be elevated cancer *risks*. (See Final ATSDR Report, April 2019, Table 2 (identifying organs with elevated cancer risks and not including the cancers at issue here).) Because Dr. Hu’s specific causation opinions contradict the authority he cites, they should be excluded. See *Concord Boat Corp.*, 207 F.3d at 1057 (an opinion that ignores relevant data should be excluded).

B. Dr. Hu Failed to Rule Out Alternative Causes.

Dr. Hu claims he performed a “differential etiology” to support his opinion, but he failed in virtually every aspect of a reliable differential etiology. A differential etiology (or differential diagnosis) is “a standard scientific technique of identifying the cause of a medical problem by eliminating other likely causes until the most probable one is isolated.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (cited with approval in *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986 (8th Cir. 2001)). A physician begins a differential etiology by “‘ruling in’ all scientifically plausible causes of the plaintiff’s injury. The physician then ‘rules out’ the least plausible causes of injury until the most likely cause remains.” *Glastetter*, 252 F.3d

¹¹ Clark admits his doses for Butler, Koterba and Walick are below 100 millirem a year. (Clark *Butler* 167:22-168:22; 210:4-7; 213:9-11). Clark does not know if Hines’s dose is below 100 millirem a year because, as he admits, he calculated Hines’s dose wrong. (Clark *Butler* 201:19-202:8).

at 989. A reliable differential etiology “typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests.” *Westberry*, 178 F.3d at 262; *see also* *Clark Czapla* 147:10–148:7, attached as **Exhibit I** (describing a specific causation opinion as requiring an assessment of the individual’s family history, job history, and other exposures); *Hu Czapla* 8/31/20, 14:17–15:1 (understanding plaintiff’s medical scan history important to know other sources of ionizing radiation).

As a threshold failure, Dr. Hu cannot reliably “rule in” radiation exposure as a possible cause of the cancers in this case because he has no reliable dose to rely on and no literature supports his opinion that Plaintiffs’ insignificant, below-background doses could possibly cause the cancers alleged. *See McMunn*, 869 F.3d at 246 n.24 (contrasting mesothelioma, which is a “signature” disease relating to asbestos exposure, with the cancers suffered by the plaintiffs in that case, which “have numerous and sometimes even unknowable causes”); *In re TMI Litig.*, 193 F.3d at 643 (“Consequently, medical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure”); *Bland*, 538 F.3d at 898 (“the gap between the data identified and [the expert’s] opinion was simply too great an analytical gap . . . to support admissibility” (internal quotations omitted)); *see also* *Clark Czapla* 23:4–19 (radiation exposure below background levels would not increase cancer risk).

Dr. Hu also conducted no physical examinations of the Plaintiffs; he did not even speak to or have contact with any of them. (*Hu Butler* 39:18–40:1.) Nor did he review the Court-mandated questionnaires, which this Court carefully approved and which detailed Plaintiffs’ potential exposure histories. (*Hu Butler* 85:8–86:6.) Dr. Hu’s overall investigation into Plaintiffs’ medical history was so limited that he only spent a total of thirty minutes reviewing the medical records for *all four* Plaintiffs and a Family History Questionnaire on cancer. (*Hu Butler* 78:8–18.)

Dr. Hu also did virtually nothing to investigate or “rule in” other potential causes of Plaintiffs’ cancers. *See, e.g.*, Risk Factors for Cancer, National Cancer Institute at the National Institute of Health (“Risk Factors”), available at <https://www.cancer.gov/about-cancer/causes-prevention/risk> (listing risk factors for cancer such as age, alcohol, cancer-causing substances, chronic inflammation, diet, hormones, immunosuppression, infectious agents, obesity, radiation, sunlight, and tobacco). For Plaintiff Anthony Hines, for example, Dr. Hu’s entire “differential etiology” consisted of determining whether he had any first-degree relative with a hematologic malignancy and whether he actually grew up on a farm. (Hu *Butler* 218:19—219:2.) Dr. Hu’s outcome-driven, half-hearted investigation did not reveal that Mr. Hines previously worked as an exterminator—which Dr. Hu admits could have exposed him to pesticides and herbicides that are known to cause Mr. Hines’ specific cancer. (Hu *Butler* 223:7–9.) Nor did Dr. Hu bother to ask Mr. Hines about his smoking history. In fact, Mr. Hines smoked a pack a day for 34 years. (Hu *Butler* 219:3–223:10.) Mr. Koterba also smoked a pack a day for 45 years. (*Id.*; Hu *Butler* 228:15–19; Koterba *Butler* Dep. 92:24–94:5, attached as **Exhibit J**.)

In short, Dr. Hu started with the assumption that the radiation exposure alleged in this case caused all the Plaintiffs’ cancers, and he ignored everything that demonstrated the assumption was incorrect. (*See, e.g.*, Hu *Czapla* 9/1/20, 31:7–22) This approach is the antithesis of science and should be stricken under *Daubert*. *See Castellow*, 97 F. Supp. 2d at 786 (“work[ing] backward” from conclusion to find scientific support is a practice that “cannot withstand *Daubert* scrutiny and is not due any credence in a court of law”).

C. Dr. Hu’s Opinion that the Plaintiffs in this Case Were Exposed to Radiation in Amounts Less Than Natural Background Is Not Relevant Under the Price-Anderson Act.

In addition to the reliability issues above, Dr. Hu’s specific causation opinion also fails the relevancy standard of *Daubert*. The standard requires that expert testimony must “fit” the relevant

issue in the case. *Daubert*, 509 U.S. at 590; *Sorensen By & Through Dunbar v. Shaklee Corp.*, 31 F.3d 638, 648 (8th Cir. 1994). But Dr. Hu’s opinion here contradicts a relevant standard of the Price-Anderson Act. His testimony would effectively nullify that legal standard—which requires a threshold showing that exposure levels exceeded the normal background level—because the doses he claims caused the Plaintiffs’ cancers, Dr. Clark’s RME and even many of Clark’s impossible “maximum” doses, are below the natural background level. *See In re TMI Litig.*, 193 F.3d at 659.

As discussed above, courts and scientific and regulatory authorities define the “natural background” level as 360 millirem *per year*. (*See supra* § A.2.) But if Drs. Clark and Hu were to use this number for background radiation, even the fictional doses Dr. Clark came up with would be legally and medically insignificant exposures in comparison. (Hu *Butler* 97:16–19; Hu April 1, 2019 Reports, Section II.B.) Therefore, Dr. Hu uses Dr. Clark’s fabricated background levels to achieve this threshold because the lower, fictitious background levels gives the false appearance of significance to Dr. Clark’s insignificant doses.

Putting the RME based doses Dr. Hu relied on in their proper context reveals how insignificant they actually are. The agreed-upon penetrating dose to an organ from natural background is 80-100 millirem per year.¹² Table 1 compares Dr. Hu’s RME doses with the appropriate organ-specific contribution from the scientifically accepted natural background (properly accounting for each plaintiffs’ actual exposure period and the relevant latent period¹³).

¹² Mettler-Royal Report, March 17, 2020, nn. 6, 9, 12, and 16.

¹³ By properly accounting for each plaintiffs’ exposure period and their relevant latency period, the natural background number presented reflects reality for each Plaintiff and is compared to Dr. Clark’s RME dose that includes 70 years of exposure (not reality). Obviously, if Defendants improperly included 70 years of exposure to natural background, like the plaintiffs included 70 years of exposures in their doses, the natural background number would be even higher.

Table 1. Plaintiffs RME Doses Compared to Natural Background

Plaintiff	Clark's Committed Dose for Exposure to Organ (mrem) (the "RME" dose)	Natural Background Dose to Organ (mrem) ¹⁴
Hines	55 - 131	3,440 - 4,300
Walick	0.956 - 2.42	1,120 - 1,400
Koterba	5.77 - 16.3	3,760 - 4,700
Butler	1.7 - 6.8	3,760 - 4,700

Because Dr. Hu's opinion does not fit—and in fact contradicts—the relevant minimum exposure requirement of the Price-Anderson Act, his testimony should be excluded under *Daubert*. *In re TMI Litig.* 193 F.3d at 659; *see also Cano* 362 F. Supp. 2d at 859.

D. Dr. Hu's Addendum Opinions Are Also Unreliable and Must Be Excluded.

On September 30, 2019, Dr. Hu issued four untimely addenda to his April 1, 2019 Reports (the "Addenda"), attached as **Exhibits K 1-4**. With no scientific underpinning, Dr. Hu's Addenda added two techniques that further inflate his numbers: (1) rather than rely on Dr. Clark's RME doses, as his original Reports had done, the Addenda rely on "maximum" doses drawn from the appendices of Dr. Clark's reports; and (2) the Addenda add a risk assessment of 1 in 1 million that contradicts the risk assessment used by both Dr. Clark and ATSDR. These dramatic changes are unreliable and, in Dr. Hu's own words, impossible. (Hu *Butler* 214:3–216:2).

1. The Maximum Doses Dr. Hu Relies on Are Impossible.

Dr. Hu's newfound use of maximum doses in his Addenda has no reliable scientific justification. The maximum doses are orders of magnitude greater than the RME based doses Dr. Clark provided to Dr. Hu for causation and Dr. Hu included in his original Reports. As discussed above, RME means reasonable **maximum** exposure. For comparison, Table 2 below displays Dr. Clark's RME dose, the "maximum" dose from Dr. Hu's Addenda, Mallinckrodt's expert's dose (the "RAC Dose"), and the dose from natural background radiation.

¹⁴ Mettler-Royal Report, March 17, 2020, nn. 6, 9, 12, and 16.

Table 2. Plaintiffs and Defendant Mallinckrodt's Exposure Doses Compared to Natural Background with Plaintiffs' Maximum Doses Included

Plaintiff	Clark Committed Dose for Exposure to Organ (the "RME" Doses) (mrem)	Clark Maximum Dose for Exposure to Organ (mrem) ¹⁵	RAC Dose (mrem)	Natural Background Dose to Organ (mrem)
Hines	55 - 131	19,300 - 43,900	494.2	3,440 - 4,300
Walick	0.956 - 2.42	21 - 71	42.6	1,120 - 1,400
Koterba	5.77 - 16.3	45.2 - 272	54.7	3,760 - 4,700
Butler	1.7 to 6.8	197 - 1,290	4.1	3,760-4,700

To generate these maximum doses, Dr. Clark looked through the thousands of radiation samples in and around Coldwater Creek to find the highest recorded measurements for Thorium-230, Radium-226, and Uranium-238.¹⁶ Critically, the highest measurements for each of these three radionuclides were from different samples taken in different geographic locations. (RAC March 17, 2020 Report, p. 14-10, attached as **Exhibit P**.) In other words, the highest measurement for thorium-230 was in a different location than the highest measurement for radium-226 and so forth. Dr. Clark's maximum dose necessarily assumes each Plaintiff was exposed at the highest reported Thorium-230 location, the highest reported Radium-226 location, and the highest reported Uranium-238 location—simultaneously for their entire exposure period.¹⁷ This assumption is obviously impossible because it requires each Plaintiff to be in three different places at the same time and assumes the Plaintiff never left those locations over the course of their entire already inflated, exposure period.

¹⁵ Doses from Hu's Addenda, September 30, 2019 for each Plaintiff.

¹⁶ See; Clark Exposure Analysis for Pamela Butler, March 31, 2019, PDF pg. 293, attached as **Exhibit L**; Clark Exposure Analysis for Anthony Hines, March 31, 2019, PDF pg. 298, attached as **Exhibit M**; Clark Exposure Analysis for Kenneth Koterba, PDF pg. 277, attached as **Exhibit N**; Clark Exposure Analysis for Walick, March 31, 2019, PDF pg. 277, attached as **Exhibit O**.

¹⁷ See Clark Exposure Analysis for Pamela Butler, March 31, 2019, Appendix C3, PDF pp. 217–293; Clark Exposure Analysis for Anthony Hines, March 31, 2019, Appendix C3, PDF pp. 277–298; Clark Exposure Analysis for Kenneth Koterba, Appendix C3, PDF pp. 206–277; Clark Exposure Analysis for Walick, March 31, 2019, Appendix C3, PDF pp. 206–277.

Dr. Hu's use of this type of maximum dose is indefensible. Dr. Hu admits: (1) it is impossible for a Plaintiff to be three different locations at one time; (2) there is no authoritative literature that uses this "maximum" dose to calculate causation; (3) Dr. Hu has never used such a maximum dose to calculate causation; (4) Dr. Hu has never seen anyone but Dr. Clark use this maximum dose to calculate causation; (5) Dr. Hu is not qualified to choose the appropriate dose to evaluate risk; and (6) Dr. Clark, the exposure assessor, identified the RME-based dose, not the "maximum" dose, as appropriate for causation analysis. (Hu *Butler* 149:7–22; 214:3–216:2; 257:25; 119:6–25; 170:2–4; 198:23–199:9; 251:19–24; 248:12–19; 254:13–22.)

Dr. Hu is on an island when it comes to reliance on this manufactured "maximum" dose. His use of this "maximum" dose was contrived for this litigation, likely because the first-calculated RME doses were indisputably insignificant. And when asked if he knew of "any federal regulatory agency that uses the max concentration to determine risk?" Dr. Hu responded, "I'm not an expert on that, and I don't know." (Hu *Butler* 251:19–24.) Because the Addenda are unreliable, Dr. Hu's testimony should be excluded on these matters.

2. Dr. Hu's Causation Threshold Contradicts Both Dr. Clark and the ATSDR.

For the first time in the Addenda, Dr. Hu also offers a mathematical threshold for risk—whether each Plaintiffs' exposure increased their risk of cancer to more than 1 in 1 million. (Hu *Butler* 118:23–119:5.) But this risk assessment suffers two fatal flaws.

First, Dr. Hu calculated the risk assessment using Dr. Clark's "maximum" numbers are flawed and unreliable for the same reasons as noted above—the scenario on which the numbers are calculated is physically impossible. (Hu *Butler* 212:14–17; *see infra* § C.1.)

Second, the threshold—1 in 1 million—contradicts the two sources Dr. Hu relies on for his opinion: Dr. Clark's Report and the ATSDR Report. (Hu *Butler* 115:8–118:16.) Both ATSDR and

Dr. Clark present risk in terms of 1 in 10,000. *Id.* Applying this risk threshold to Dr. Clark's RME doses shows no increase in risk. For example, Dr. Clark calculated Mr. Hines's risk of cancer from the RME doses at 0.2 to 0.4 in 10,000 and Ms. Butler's risk of cancer from the RME doses at 0.01 to 0.02 in 10,000. (*See* § 4 of Clark's Report for each plaintiff.) Dr. Clark could not even calculate a threshold for Mr. Walick and Mr. Koterba. (Clark *Butler* 200:13–19; 213:6–8.) Faced with these insignificant and non-existent risk assessments, Dr. Hu's only choice (if his goal were to find causation rather than provide a scientific assessment) was to artificially increase the RME doses to maximum doses and then also decrease the assessment threshold from 1 in 10,000 to 1 in 1 million. Therefore, Dr. Hu's opinions must be excluded because “work[ing] backward” from a conclusion to find scientific support “cannot withstand *Daubert* scrutiny and is not due any credence in a court of law.” *Castellow*, 97 F. Supp. 2d at 786.

E. Dr. Hu Is Ultimately Not Qualified to Opine on Specific Causation.

Dr. Hu is not qualified to opine on specific causation. Specific causation in this case involves rendering an opinion on whether the Plaintiffs' exposure to the radiation at issue was responsible for the specific types of cancer these Plaintiffs developed. Dr. Hu admits that he is not an expert in the fields necessary to offer a specific causation opinion in this case. *See Ralston v Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (“Merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issues”). Specifically, Dr. Hu is not an expert in health physics, radiation sources, calculating risk from dose concentrations, or oncology (generally or specific to radiation, breast cancer, lymphoma, or brain cancer). (Hu *Strong* Dep. Vol. I 18:8–20:9; Hu *Butler* Dep. at 27:14–29:3.) Dr. Hu's websites at

the University of Washington and the University of Michigan do not mention radiation as an area of his expertise.¹⁸

Dr. Hu also admits that he has no peer-reviewed journal articles on the health effects of radiation. (Hu *Strong* Vol. II at 8:8–14; 13:4–7, attached as **Exhibit Q**.) Dr. Hu’s experience with ionizing radiation (to say nothing of the ability of particular radionuclides to cause specific cancers in humans) is limited to his having taken two single-semester courses forty years ago. (Hu *Butler* 22:16–23:7.) This experience—two single-semester courses—does not approach the level of “intellectual rigor that characterizes the practice of an expert in the relevant field.” *Omega Flex, Inc.*, 783 F.3d at 722.

Despite rendering an opinion on a radiation dose’s ability to cause cancer, Dr. Hu has no familiarity with common doses or regulatory limits. He could not even describe the very dose Dr. Clark calculated in this case and on which his opinion relies:

Q. What is committed effective dose?

A. It has to do with how the dose relates to the radionuclides and the penetrating power of each of the radionuclides in terms of alpha radiation, beta radiation, etcetera.

Q. And that’s actually committed equivalent dose, isn’t it?

A. Like I said, I have to parse through my references to give you an exact answer.

(Hu *Butler* 48:3–11; *see also* Hu *Czapla* 8/31/20, 70:14–72:10; Mettler-Royal March 17, 2020 Report, pp. 17–19, citing Hu *Butler* 46:7–25, 47:16–19, 47:25–48:14, 52:24–53:4.)

He also does not know the basics of radiation science: common doses from common medical examinations like x-rays or CT scans, the universally accepted level of natural background

¹⁸ See <https://sph.umich.edu/faculty-profiles/hu-howard.html>; <https://deohs.washington.edu/faculty/howard-hu>.

radiation to which humans are subjected annually, regulatory limits for radiation, or even basic terminology:

Q. Okay. Do you know what the current U.S.-recommended maximum permissible whole-body dose of external radiation is for the general public?

A. I've seen that number, but I don't recall what it is specifically.

(Hu *Butler* 158:22–159:2.)

Q. Okay. Doctor, in your opinion, what would be a fair estimate of the radiation exposure from a whole body CT?

A. I don't have an opinion on that. I haven't delved into that subject at any length.

(Hu *Strong* v.1, 70:22–71:1.)

Q. What is the effective dose to the brain from natural background every year?

A. I'd have to look at the ICRP reports to see if those statistics are available.

Q. Okay. Would it surprise you if it was 100 millirem?

A. It could be.

Q. The same for breast and lymph nodes?

A. I'd have to see the statistics to give an opinion on that.

(Hu *Butler* 112:7–16.)

Dr. Hu's lack of "knowledge, skill, experience, training, or education," coupled with his failure to grasp basic concepts in the field, preclude him from rendering a specific causation opinion in this case. Fed. R. Evid. 702; *see also Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 929 (D. Minn. 2014) (excluding a dentist from testifying to medical causation because he did not prescribe, speak on, research, or write regarding the treatment at issue, and he was not an oncologist). The sole basis for Dr. Hu's knowledge—the "mere reading of others' articles"—is not

sufficient to qualify him as an expert. *Id.* Dr. Hu's causation opinions should thus be excluded based on his lack of qualifications on those topics.

V. CONCLUSION

For the reasons stated above, Dr. Hu's proffered expert opinions do not meet the requirements for admissibility under Federal Rule of Evidence 702 or the *Daubert* line of cases. Therefore, Mallinckrodt and Cotter respectfully request this Court enter an Order excluding his opinions and testimony.

Dated: August 18, 2021

Respectfully submitted,

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I hereby certify that on the 18th day of August 2021, I served the above to the following counsel of record via the Court's electronic filing system.

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